

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Richmond Division**

ROBERT BLANCO,	)	
Plaintiff,	)	
	)	
v.	)	Civ. Action No.: 3:10-cv-0033-JRS
	)	
WYETH, INC.,	)	
f/k/a American Home Products Corporation,	)	
WYETH PHARMACEUTICALS, INC.,	)	
f/k/a Wyeth-Ayerst Pharmaceuticals, Inc.,	)	
f/k/a Wyeth Laboratories, Inc.	)	
Defendants.	)	

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**WYETH’S MEMORANDUM IN SUPPORT OF ITS MOTION *IN LIMINE* TO  
EXCLUDE THE TESTIMONY OF KEITH ALTMAN**

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Defendants Wyeth LLC (incorrectly identified in Plaintiff’s Complaint as Wyeth Inc., f/k/a American Home Products Corporation) and Wyeth Pharmaceuticals Inc. (incorrectly identified in Plaintiff’s Complaint as Wyeth Pharmaceuticals, Inc., f/k/a Wyeth-Ayerst Pharmaceuticals, Inc., f/k/a Wyeth Laboratories, Inc.) (collectively, “Wyeth”), by counsel, state as follows in support of their Motion *In Limine* to Exclude the Testimony of Keith Altman.

**PRELIMINARY STATEMENT**

Wyeth hereby moves under Federal Rules of Evidence 702 and 1006 to preclude plaintiff’s expert Keith Altman from testifying in this matter. Plaintiff has named Mr. Altman as a generic expert witness who will testify in the trial of this matter. It is anticipated that Mr. Altman will testify as to certain summaries he was directed to create by various plaintiffs’ counsel in the diet drug litigation. Mr. Altman has reviewed information he obtained from plaintiffs’ lawyers about Wyeth’s internal adverse drug event (“ADE”) reporting systems and purportedly re-organized the information into his own summary format.

Everything Mr. Altman claims to know about the subjects in these summaries he has learned as a litigation consultant for plaintiffs in the diet drug litigation. However, Mr. Altman's "expert report," submitted in this case on May 30, 2008 does not include these summaries, though they are referenced in the report, and furthermore contains no opinions or conclusions on the data he reviewed. In fact, the report expressly disclaims that Mr. Altman intends to offer any expert opinions at all.<sup>1</sup> He took whatever Plaintiff's counsel gave him and performed computer searches on it. He then arrayed certain data he found into charts, the format of which was dictated by Plaintiff's counsel.

As set forth below, Wyeth challenges the admissibility of Mr. Altman's testimony, as his experience as a litigation computer specialist does not provide him with the necessary expertise to give testimony under Federal Rules of Evidence 702 or 1006.<sup>2</sup> Wyeth also challenges Mr. Altman's designation as an expert because his "expert report" does not comply with Federal Rule of Civil Procedure 26(a)(2)(B).

## **FACTUAL BACKGROUND**

### **I. Keith Altman's Background**

Keith Altman is a computer technician acting as a litigation consultant to plaintiffs' law firms involved in various mass-tort suits. *See* Report of Keith L. Altman (attached as **Exhibit A**); Altman Curriculum Vitae (attached as **Exhibit B**); Deposition of Keith Altman, 3/4/05, at 32 (attached as **Exhibit C**) (his activities are "generally connected with plaintiff litigation"). He is

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<sup>1</sup> By letter dated May 30, 2008, Plaintiff designated Mr. Altman as a generic expert in this case, and submitted, by agreement, the February 20, 2008 generic expert report prepared in Stribling case (attached as Exhibit E).

<sup>2</sup> Nor can Mr. Altman qualify to offer opinion testimony under Federal Rule of Evidence 701 as he is not a percipient fact witness of any events at issue in this case.

employed by Finkelstein & Partners, “a plaintiffs’ personal injury firm.” *See* Deposition of Keith Altman, 10/2/03, at 40 (attached as **Exhibit D**). He works solely for plaintiffs in civil cases. Ex. C at 42-43 (“I’ve not ever worked for the defense in a personal injury context”). He has an undergraduate degree in astrophysics—a totally irrelevant field—and no further degrees. Ex. B; Ex. C at 53 (“adverse event systems” are “not astrophysics”). Mr. Altman:

- Has no formal education at any level concerning computers except one class, a “tutorial” on an unrelated, obscure programming language called APL. Ex. D at 13-14.
- Despite immeasurable advances in computer technology, has taken no computer-related courses in the last eighteen years. *Id.* at 14-15 (only computer course, the APL tutorial, was in 1986 or 1987).
- Has never taken any course in mathematical or computer modeling. *Id.* at 12 (never taken any data modeling courses).
- Has no degree related to computer science or data processing. *Id.* at 11.
- Has no degree in mathematics. *Id.*
- Has no advanced degrees. *Id.* (received no further education after college).
- Lacks any graduate or postgraduate education in any relevant field. *Id.* at 12-13.<sup>3</sup>
- Has never taught any course, or portion of a course, anywhere. *Id.* at 54.
- Is not a doctor. Ex. C at 55.
- Has no relevant experience in the pharmaceutical industry or in analysis of ADEs for other than litigation purposes. Ex. D at 43.

All of Mr. Altman’s purported “expertise” has come through working for plaintiffs’ lawyers.

Until becoming involved in diet drug litigation, he “did not” have any experience with “databases used to track ADEs or analyze ADEs.” Ex. D at 21-22. He has never been an

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<sup>3</sup> Mr. Altman subsequently testified that he has recently started taking online classes with an Internet-based correspondence-only law school. Ex. C, at 41.

employee of any pharmaceutical company, or done any work directly for such a company. Ex. C, at 35. He has never worked for the FDA or served on any FDA committee. Ex. D at 17.<sup>4</sup>

## II. Keith Altman's "Methodology"

According to his report, Mr. Altman's job in the diet drug litigation has been to create various summaries of Wyeth ADE databases at the behest of plaintiffs' counsel. To create a summary, Mr. Altman begins with a query, most often from a plaintiff's lawyer. Ex. C at 12 ("Q: And then there are certain reports that you run at the request of attorneys; is that right? A: That's correct."); *id.* at 32 ("Q: You have been asked to do reports for a plaintiff by plaintiff's lawyers or people working for plaintiff's lawyers? A: I think the vast bulk of them, that's true."). He then runs searches in various databases and compiles charts with the results. Mr. Altman makes decisions on which fields to include in particular reports, not based on any medical or scientific knowledge, which he does not possess, but based on what the lawyer wants to know and what "seems" to Mr. Altman to be relevant. Ex. D at 106 ("Q: But when you say you included everything in the database you certainly didn't include all the fields? A: I didn't, no."); *id.* at 108 ("Q: Who picked the fields to include on Exhibit Three? A: I did. Q: And that was an exercise of judgment on your part? A: I was asked to decide whether [the ADE] was serious and labeled. I was asked to put down what date it was, and those were dates and the fields that seemed to comply with that.").

As a litigation consultant, the "reports" Mr. Altman produces are "run at the request of attorneys," as is all other ADE-related "work" he has done. Ex. C at 12. Mr. Altman does not even look at the underlying ADEs. *Id.* at 90 ("Q. Have you looked at the underlying reports? A.

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<sup>4</sup> He claims only that on one occasion the Agency accepted his unsolicited advice. Ex. C, at 40.

No.”); *id.* (“I have not looked at the underlying reports”); *id.* at 126 (“Q . . . [Y]ou did not attempt to review the underlying reports for any substance? A. No. . . .”).

Mr. Altman prepares his reports on valvular heart disease (“VHD”) ADEs with “no idea how [Wyeth] used the term valvular heart disease,” thus including ADEs that do not have clinically significant levels of regurgitation. *Id.* at 101, 108-109, 173. He operates with no exclusion criteria at all. *Id.* at 175 (“Q. And you obviously . . . didn’t have any exclusion criteria, did you? A. No.”). Instead, he uses whatever is in a database supplied by counsel, making no effort to understand how or why any of the ADEs were created. *Id.* at 79 (“That’s the database that was provided. If it’s in there, it’s in there. If it’s not, it’s not”); *id.* at 90 (“The database is what the database shows”); *id.* at 157 (“I can only go by what’s in your database”). Over and over again, Mr. Altman displays rote, unthinking acceptance of whatever data he is given. *See id.* at 72:1-6, 73:20-24, 74:18-75:23, 79:24-80:8, 88:15-21, 89:10-19, 91:1-21, 101:7-102:1, 103:5-11, 103:19-23, 132:20-133:5, 136:12-22, 140:13-141:9, 142:13-143:4, 145:6-11; 148:10-23, 154:25-155:9, 155:22-156:16, 157:23-158:4; 159:4-20, 168:10-21, 179:4-11, 180:23-181:10, 183:21-184:9, 197:5-10. For instance, in creating his summaries, Mr. Altman does nothing to eliminate duplicate ADEs or ADEs resulting from a lawsuit. *Id.* at 29-32.

Mr. Altman claims he has reviewed certain electronic data from Wyeth’s internal computer system called the Clinical Data Safety Surveillance System (“CDSSS”) and the S<sup>3</sup> system that contains the electronic versions of Wyeth’s ADEs on Pondimin and Redux. *See Ex. A.* He also reviewed paper files on certain ADEs. *Id.* As set forth below, and in Mr. Altman’s own words, he is “not an ‘expert witness.’” However, there is no provision within the Federal Rules for testimony before the jury from a witness who is neither possessed of personal knowledge of relevant facts nor offering opinions based on relevant expertise and a reliable

methodology. There is no “other” category into which Mr. Altman can be fit and permitted to testify. He is essentially a non-witness.

## **ARGUMENT**

### **I. Legal Standard for Evaluating Expert Testimony**

A federal district court judge must play “a gatekeeping role” when considering the admissibility of expert testimony or evidence. *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 597 (1993). Because expert witnesses, unlike lay witnesses, may offer opinions that are not based on first-hand knowledge or perceptions, *compare* Fed. R. Evid. 702 *with* Fed. R. Evid. 701, and because “expert evidence can be both powerful and quite misleading,” *Daubert*, 509 U.S. at 595, district courts must determine the admissibility of expert testimony as a preliminary matter under Federal Rule of Evidence 104(a). *See id.* at 592; *Cavallo v. Star Enterprise*, 892 F. Supp. 756, 761 (E.D. Va. 1995) (Ellis, J.), *aff’d in part rev’d in part sub. nom.*, 100 F.3d 1150 (4th Cir. 1996). Federal Rule of Evidence 702 is “the primary locus,” *Daubert*, 509 U.S. at 589, 125 L. Ed. 2d at 482, of a district court’s discharge of its “gatekeeping responsibility.” *Id.* at 480 n.7. Rule 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

The *Daubert* Court identified two critical components to Rule 702. First, to be admissible, an expert’s testimony must be scientific knowledge. This requirement “establishes a standard of evidentiary reliability,” or “trustworthiness,” *Daubert*, 509 U.S. at 589-90 and n.9, in the sense of “scientific validity.” *Cavallo*, 892 F. Supp. at 761. To qualify as scientific, an

expert's testimony must be "ground[ed] in the methods and procedures of science." *Daubert*, 509 U.S. at 590; *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir.), *cert. denied*, --- U.S. ---, 132 L. Ed. 2d 871 (1995); *Cavallo*, 892 F. Supp. at 760-61. To be considered knowledge, it must "connote[] *more than subjective belief or unsupported speculation*." *Daubert*, 509 U.S. at 594 (emphasis added); *Oglesby v. General Motors Corp.*, 190 F.3d 244, 250 (4<sup>th</sup> Cir. 1999) ("A reliable expert opinion must be based on scientific, technical or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or other valid methods.") (emphasis in original); *Cavallo*, 892 F. Supp. at 761. In *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4<sup>th</sup> Cir. 2001), the court reaffirmed that the purpose behind *Daubert*'s focus on reliability is to "make certain that an expert ... employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."

The second critical component to Rule 702 is the requirement that expert testimony assist the trier of fact. This condition to admissibility amounts to a special rule of relevance regarding expert testimony. *See Daubert*, 509 U.S. at 591; *Cavallo*, 892 F. Supp. at 760. To be admissible, an expert's testimony must have "a valid scientific connection to the pertinent inquiry...." *Daubert*, 509 U.S. at 592-93. In short, the scientific validity of the expert's testimony must "fit" the purpose for which it is used, because "scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." *Id.* at 591; *Cavallo*, 892 F. Supp. at 761.

As this Court has stated, "[t]he distinction between 'scientific validity' and 'fit' is not always clear, and the two inquiries may overlap in a particular case." *Cavallo*, 892 F. Supp. at 761. Thus,

[a]lthough courts must not exclude expert testimony based on a valid methodology simply because they disagree with the ultimate conclusion reached, they *have an obligation to ensure that the conclusion is reliable*, that is, that there is a *scientifically valid link* between the sources or studies consulted and the conclusion reached.

*Cavallo*, 892 F. Supp. at 762 (emphasis added). The Supreme Court reaffirmed these principles in *General Electric Co. v. Joiner*, 118 S. Ct. 512, 517 (1997), in which it observed:

[C]onclusions and methodologies are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert.

*Joiner*, 118 S. Ct. at 519.

In *Kumho Tire Co. v. Carmichael*, 119 S. Ct. 1167 (1999), the Supreme Court reiterated the importance of *Daubert*'s gatekeeping requirement. Although the Court recognized in that case that a trial court has "considerable leeway" in analyzing disputed expert testimony, *see Kumho Tire*, 119 S. Ct. at 1176, "discretion in choosing the manner of testing expert reliability is not discretion to abandon the gatekeeping function ... [or] discretion to perform the function inadequately." *Id.* at 1179 (Scalia, J., concurring). Indeed, as the author of the *Kumho Tire* opinion noted in *Joiner*: "[N]either the difficulty of the task nor any comparative lack of expertise can excuse the judge from exercising the 'gatekeeper' duties that the Federal Rules of Evidence impose – determining, for example, whether particular expert testimony is reliable and 'will assist the trier of fact.' " *Joiner*, 522 U.S. at 148 (Breyer, J. concurring). A Virginia federal court has interpreted the mandate from *Kumho Tire* as follows:

While there are certainly times when, given the complexity of issues or the ferocity of the debate, it may seem expedient just to let opposing experts do battle at trial, the Supreme Court has made



clear that to do so, without due circumspection, would be shirking my duty as evidentiary ‘gatekeeper’ to the trial process.

*Hartwell v. Danek Medical Inc.*, 47 F. Supp. 2d 703, 711 (W.D. Va. 1999).

**II. Altman is Not an Expert and Should Not Be Permitted to Offer Any Purported “Expert Testimony.”**

Mr. Altman is not an expert. Mr. Altman submitted an “expert report” dated February 20, 2008 in which he admits that he is not an expert witness. *See* 2/20/08 Report of Keith L. Altman (attached as **Exhibit A**). Under the “Conclusion” paragraph of the report, Mr. Altman states:

I am not an “expert witness” in the sense of [Rule] 26, because I will be testifying as to facts, not opinions, although I will use technical expertise to summarize those facts. I have technical expertise to provide summary testimony. This notice allows defendant’s sufficient time to cross-examine me on my findings and summaries. The summaries linked to the original images of documents, complete with AHP bates numbers, are available in the office of plaintiff’s counsel upon reasonable notice.

*Id.* at 5.

Despite acknowledging that Mr. Altman is not an expert, Plaintiff nevertheless designated Mr. Altman as one of his generic experts to “testify[] as to facts, not opinions.” *See* Ex. A at 2. Yet, Mr. Altman does not possess either the first-hand knowledge necessary to testify as a fact witness or the technical expertise and experience required to offer expert opinion testimony under Federal Rule of Evidence 702.

In truth, plaintiffs, including Plaintiff in this case, attempt to use Mr. Altman not as a fact witness or a bona fide expert witness, but rather as a mere conduit for the introduction of otherwise inadmissible hearsay evidence. Federal courts have consistently recognized that such

testimony is improper and inadmissible under Federal Rule of Evidence 702. *See, e.g., U.S. v. Tipton*, 269 Fed. Appx. 551, 2008 U.S. App. Lexis 6232 at \*\*23 (6<sup>th</sup> Cir. 2008) (excluding defendants' expert as a "conduit" for the admission of [defendants'] otherwise inadmissible hearsay statements . . ."). *Hutchinson v. Groskin*, 927 F.2d 722, 725 (2d Cir. 1991) (excluding defendant's expert on grounds that he was being "used . . . as a conduit for hearsay testimony" from other experts); *United States v. Stone*, 222 F.R.D. 334, 341 (E.D. Tenn. 2004) ("the trial court . . . must ensure that the expert witness is truly testifying as an expert and not merely serving as a conduit through which hearsay is brought before the jury."). This Court should similarly preclude Mr. Altman from serving as a conduit for the admission of otherwise inadmissible hearsay evidence in the form of purported expert testimony.

### **III. Altman is Not Qualified to Offer Expert Opinions.**

Mr. Altman should be prohibited from providing expert testimony as he is not qualified to render an opinion on any relevant issue. As detailed above, Mr. Altman does not possess any demonstrated professional capacity to assess the scientific significance of the underlying ADE data, he does not apply any scientific methodology (much less a reliable scientific methodology), and he concedes as much in his report. *See supra* section I, Keith Altman's Background; *see also* Exs. A and E. Therefore, he is not qualified "by knowledge, skill, experience, training or education" so as to offer opinion testimony under Federal Rule of Evidence 702 and *Daubert*. *See* Fed. R. Evid. 702; *Daubert*, 509 U.S. at 590; *Hartwell*, 47 F. Supp. 2d at 715 (stating "expert qualification . . . underpins all of the factors enumerated" in *Daubert* and excluding plaintiff's unqualified experts); *see also Rubanick v. Witco Chem. Corp.*, 125 N.J. 421, 450 (1991) (an "expert must possess a demonstrated professional capability to assess the scientific significance

of the underlying data and information, to apply the scientific methodology, and to explain the bases for the opinion reached”).

#### **IV. Altman’s Summaries are Inaccurate and Not Helpful to the Jury.**

Federal Rule of Evidence 1006 provides that “[t]he contents of voluminous writings, recordings, or photographs which cannot conveniently be examined in court may be presented in the form of a chart, summary, or calculation.” Fed. R. Evid. 1006. “The purpose of this Rule is to reduce the volume of written documents that are introduced into evidence by allowing in evidence *accurate derivatives* from the voluminous documents.” *United States v. Janati*, 374 F.3d 263, 272 (4<sup>th</sup> Cir. 2004) (emphasis added) (to comply with Rule 1006, “a chart summarizing evidence must be an *accurate* compilation of the voluminous records sought to be summarized”) (emphasis in original). Although plaintiff’s counsel has not produced a report by Mr. Altman, previous summaries prepared by Mr. Altman for diet drug plaintiffs were not accurate compilations by Mr. Altman’s own testimony. *See e.g.* Ex. D at 170 (“Q: And with respect to three, four, and five, you’re not saying that these documents are a fair and accurate summary of all information in the CDSSS about valvular heart disease, pulmonary hypertension or Alopecia, are you? A: That was not the purpose.”).

To create accurate summary compilations of the underlying ADE data, Mr. Altman must have some relevant experience in the pharmaceutical industry or in analysis of ADEs for other than litigation purposes, which he does not.<sup>5</sup> *See supra* Section I, Keith Altman’s Background (before the diet drug litigation, he did not have any experience with ADE databases and has

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<sup>5</sup> For his charts to be accurate and helpful, Altman at least should have some have specialized and advanced education and training in mathematical or computer modeling, computer science or data processing, which he does not. *See supra* Section I, Keith Altman’s Background.

never worked for a pharmaceutical company or the FDA). Similarly, for Mr. Altman to create accurate summaries of Wyeth's ADE data, his methodology must be sound, which it was not. *See supra*, Section II, Keith Altman's "Methodology" (he made decisions about which fields to include in his reports and to decide whether ADEs were "serious and labeled", without any medical or scientific knowledge, without any understanding for relevant clinical terms, without exclusion criteria and without even looking at the underlying ADEs). Thus, it is improper for Mr. Altman, an unqualified witness, to testify regarding summaries that are inaccurate and insufficient under Federal Rule of Evidence 1006. Further, Federal Rule of Evidence 702, requires "technical or specialized knowledge [that] will assist the trier of fact to understand the evidence." Fed. R. Evid. 702. Mr. Altman possesses no such knowledge. Thus, summaries of voluminous ADEs prepared by Mr. Altman will not be helpful to the jury and should be excluded on that basis.

## CONCLUSION

For the reasons stated above, Wyeth respectfully requests that Court enter an order excluding the testimony of Mr. Keith Altman.

WYETH, INC., and  
WYETH PHARMACEUTICALS, INC

By: /s/  
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**CERTIFICATE OF SERVICE**

I hereby certify that on this 15th day of July, 2010, a true copy of the foregoing will be filed electronically with the Clerk of Court using the CM/ECF system, which will send a notification of such filing (NEF) to the following:

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